

the specifications to which they are represented to be manufactured,

(b) Provides for accreditation of laboratories engaged in fastener testing; and

(c) Requires inspection, testing and certification, in accordance with standardized methods, of fasteners covered by the Act.

(d) *Delegations of authority.* The Secretary of Commerce has delegated authority to the Director, National Institute of Standards and Technology to promulgate regulations in this part under sections 5 through 8 of the Fastener Quality Act (15 U.S.C. 5404-5407). In addition, the Secretary of Commerce has delegated concurrent authority to the Under Secretary for Export Administration to amend the regulations issued under sections 5 through 7 of the Act, regarding enforcement. The Secretary of Commerce has also delegated concurrent authority to amend the regulations issued under section 8 of the Act, regarding recordal of insignias, to the Assistant Secretary and Commissioner of Patents and Trademarks.

[61 FR 50558, Sept. 26, 1996, as amended at 63 FR 18271, Apr. 14, 1998]

§ 280.2 Definitions.

Unless the context requires otherwise or unless specifically stated the terms in this part have the meanings prescribed in the statute. In addition the following definitions apply.

Accreditation for purposes of the Act and this part means accreditation of a testing laboratory or the registration of a fastener manufacturing facility employing a quality assurance system (a Facility).

Accreditation body refers to the National Voluntary Laboratory Accreditation Program and those private entities currently approved by NIST under subpart D of this part and those foreign governments or organizations currently recognized by NIST under subpart E of this part.

Accreditation criteria means a set of requirements used by an accreditation body which a laboratory must meet to be accredited.

Accredited registrar means a registrar, as defined in this part, that is accredited by a recognized accreditor and ap-

pears on the Registrars List described in section 280.810(b).

Accreditor means a Registrar accreditation body that meets the requirements of subpart K of this part.

The Act means the Fastener Quality Act (Pub.L. 101-592, as amended by Pub.L. 104-113).

Alter means to alter by through hardening; by electroplating of fasteners; or by machining.

Alteror means a person who owns a fastener and causes it to be altered.

Approved signatory is an individual employed by a laboratory accredited under the Act and these regulations who is recognized by an accreditation body as competent to sign accredited laboratory test reports.

Authorized representative means an employee of an organization who is authorized by that organization to speak on its behalf for purposes of the Act and this part.

Bureau of Export Administration or (BXA) means the Bureau of Export Administration of the United States Department of Commerce, including the Office of Export Enforcement.

Certificate of accreditation is a document issued by an accreditation body to a laboratory that has met the criteria and conditions of accreditation. The certificate, together with the assigned code number, and scope of accreditation issued by the accreditation body may be used as proof of accredited status.

Certified copy (of a laboratory testing report) means a complete and accurate copy of the original laboratory testing report, which contains a statement describing it as an accurate and complete copy of the original and which is signed by an authorized representative of the accredited laboratory issuing the report or, in the case of metal chemistry testing reports, an authorized representative of the metal manufacturer.

Commingling means the mixing of fasteners from different lots in the same container.

Commissioner means the Commissioner of Patents and Trademarks.

Consensus standards organization means the American Society for Testing and Materials (ASTM), American National Standards Institute (ANSI),

American Society of Mechanical Engineers (ASME), Society of Automotive Engineers (SAE), or any other consensus standards setting organization (domestic or foreign) publicly identified by NIST as having comparable knowledge, expertise, and concern for the health and safety in the field for which such organization purports to set standards.

Container means any package of fasteners traded in commerce.

Date of manufacture means that date upon which the initial conversion of material into a fastener takes place.

Director means the Director of the National Institute of Standards and Technology (NIST).

Facility means a fastener manufacturing facility, or a facility performing subcontracted processes for a fastener manufacturing facility, implementing a fastener quality assurance system as defined in this part.

Fastener means any screw, nut, bolt or stud, washer or other item included within the definition for fastener contained in section 3(5) of the Fastener Quality Act. The term “fastener” does not include a screw, nut, bolt, or stud:

- (1) That is produced and marked as ASTM A307 Grade A;
- (2) That is produced in accordance with ASTM F432; or
- (3) That is held out as being produced to other than the provisions of standards and specifications published by a consensus standards organization, or a government agency.

A screw, nut, bolt, stud or washer held out as being produced according to requirements of a document other than a document published by a consensus standards organization is a fastener within the meaning of the Act and this part if that document incorporates or references (directly or indirectly) standards and specifications published by a consensus standards organization or government agency for purposes of delineating performance or materials characteristics of the fastener.

Fastener insignia register means the register established at the U.S. Patent and Trademark Office for the recordal of fastener insignia to identify the manufacturer or private label distributor.

Fastener Quality Assurance System (QAS)—(1) *Fastener Quality Assurance System (QAS)* means a fastener manufacturing system that has as a stated goal the prevention of defects through continuous improvement, and which seeks to attain that goal by incorporating:

- (i) Advanced quality planning;
- (ii) Monitoring and control of the manufacturing process;
- (iii) Process inspection embodied in a comprehensive and written control plan for product/process characteristics, process controls (including statistical process control), tests, and measurement systems that will occur during mass production; and
- (iv) The creation, maintenance, and retention of electronic, photographic, or paper records, available for inspection during the periods required by section 10 of the Act and §280.7 of this part, regarding the inspections, tests, and measurements required by or performed pursuant to the control plan.

(2) A Fastener Quality Assurance System contains the following elements at a minimum:

- (i) A documented quality management system that satisfies the requirements of ISO-9001 “Quality Systems—Model for quality assurance in design, development, production, installation and servicing,” ISO-9002 “Quality Systems—Model for quality assurance in production, installation and servicing,” or other quality system standards that incorporate ISO-9001 or ISO-9002 (e.g. QS-9000, AS-9000, etc.);
- (ii) A requirement that raw material certification supplied to the fastener manufacturer shall be traceable to that of a mill heat of material that has been tested by a laboratory on the Accredited Laboratory List;
- (iii) A requirement that subcontracted processes, including plating and heat treating, are controlled by the manufacturer, to avoid product lot contamination, and that finished lots of fasteners shall be traceable to subcontracted processes performed by a registered Facility on the Facilities List described in §280.810 or tested by a Laboratory on the Laboratories List described in §280.101;
- (iv) A requirement that the fastener manufacturer fully document fastener

sampling and inspection points and an in-process control plan that emphasizes defect prevention, relates frequency of inspection, corrective action for non-conforming characteristics, and sampling frequency and sample size; a requirement that the control plan be made available to the customer upon request and shall identify those standards and specifications upon which the plan is based; and

(v) A requirement that the in-process control plan include those characteristics specified by the QAS standard, characteristics specifically indicated by applicable fastener standards and specifications, and those characteristics as designated by the end user for evaluating product functionality.

Fastener set means a collection of small quantities of products, including fasteners, of varying sizes, collected together and sold as a package.

Grade or property class identification marking means any symbol appearing on a fastener purporting to indicate that the fastener's base material, strength properties, or performance capabilities conform to a specific standard of a consensus standards organization or government agency. A raw material mark is not considered as a grade identification mark for purposes of these regulations unless this mark is required by the fastener standards and specifications to identify specific conformance.

Importer means a person located within the United States who contracts for the initial purchase of fasteners manufactured outside the United States for resale or such person's use within the United States.

Laboratory accreditation is the formal recognition that a testing laboratory is competent to carry out specific test(s) or specific type(s) of tests.

Laboratory accreditation body means a legal or administrative entity that accredits laboratories.

Laboratory assessment means the on-site examination of a testing laboratory to evaluate its compliance with specified criteria.

Laboratory test report means a report prepared by an accredited laboratory in accord with §280.6.

Lot means a quantity of fasteners of one part number fabricated by the

same production process from the same coil or heat number of metal as provided by the metal manufacturer and submitted for inspection and testing at one time.

Lot number means a number assigned by a manufacturer to the lot.

Lot-specific identification information means information applicable to a fastener consisting of, at a minimum:

(1) The part number (or a part description if there is no applicable part number),

(2) The identity of the manufacturer, and

(3) The lot number.

Lot traceability means the recording and maintenance of lot-specific identification information sufficient to trace fasteners from a single lot throughout:

(1) The manufacturer's fabrication or alteration process,

(2) All inspection and testing operations, and

(3) The subsequent chain of distribution in commerce.

Manufacturer means a person who fabricates fasteners, who significantly alters fasteners, or who alters any item so that it becomes a fastener.

NIST means the National Institute of Standards and Technology, U.S. Department of Commerce.

NVLAP means the National Voluntary Laboratory Accreditation Program operated by the National Institute of Standards and Technology.

Original laboratory testing report means: (1) In general, a laboratory testing report which is originally signed by an approved signatory or is a copy thereof, certified by the laboratory that conducted the test; or

(2) For purposes of the alternative procedures for chemical characteristics described in section 5(d) of the Act and §280.15 of this part only, a laboratory testing report which is originally signed by an approved signatory or is a copy thereof, certified by the laboratory that conducted the test or by the metal manufacturer.

Person means any individual, partnership, limited partnership or corporate entity and/or a representative, agent or designee.

Private label distributor means a person who contracts with a manufacturer for the fabrication of fasteners bearing

§ 280.3

the distributor's distinguishing insignia.

Product includes any type or category of manufactured goods, constructions, installations, or natural or processed materials.

Proficiency testing means the determination of laboratory testing performance by means of comparing and evaluating tests on the same or similar items or materials in accordance with predetermined conditions.

Recognized accreditor means an accreditor, as defined in this part, that is recognized by NIST and appears on the Accreditors List described in § 280.810(a).

Registered facility means a facility, as defined in this part, that is registered by an accredited registrar and appears on the Facilities List described in § 280.810(c).

Registrar means a quality systems Registrar that meets the requirements of subpart L of this part.

Registration means evaluation and certification of a manufacturing facility as competent to carry out and conforming to the applicable requirements of a Fastener Quality Assurance System when such evaluation and certification is performed by a Registrar as defined in this part.

Scope of accreditation is a document issued by an accreditation body to an accredited laboratory which lists the test methods, standards or specifications for which the laboratory is accredited.

Secretary means the Secretary of Commerce.

Significantly alter means to alter or take any other action which could weaken or otherwise materially affect the performance or capabilities of the fastener as it was originally manufactured, grade or property class marked, tested, or represented. The term does not include the application of adhesives or sealants, locking elements, provisions for lock wires, coatings and platings of parts having a minimum specified Rockwell C hardness of less than 32, or cutting off of fasteners. The cutting of finished threaded rods, bars or studs to produce individual smaller length threaded studs for resale is not a significant alteration. However, cut threaded studs, rods, and bars offered

15 CFR Subtitle B, Ch. II (1–1–99 Edition)

for sale shall be individually marked with the grade or property class identification marking appearing on or accompanying the original threaded studs, rods, and bars from which the fasteners were cut.

Standards and specifications means the provisions of a document published by a consensus standards organization, or a government agency.

Tamper-resistant system means the use of special paper or embossing stamps or other controls which discourage, prevent or minimize alteration of test reports subsequent to manufacturing, inspection and testing.

Testing laboratory is a laboratory which measures, examines, tests, calibrates or otherwise determines the characteristics or performance of products.

Through-harden means heating above the transformation temperature followed by quenching and tempering for the purpose of achieving a uniform hardness.

Traceability of measurements means a documented chain of comparisons connecting the accuracy of a measuring instrument to other measuring instruments of higher accuracy and, ultimately, to a primary standard.

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§ 280.3 Relationship to State laws.

Nothing in the Act or these regulations shall be construed to preempt any rights or causes of action that any buyer may have with respect to any seller of fasteners under the law of any State, except to the extent that the provisions of the Act or these regulations are in conflict with such State law.

§ 280.4 Commingling of fasteners.

(a) No manufacturer, importer, or private label distributor may commingle fasteners of the same type, grade, and dimension from different lots in the same container; except that such manufacturer, importer, or private label distributor may commingle fasteners of the same type, grade, and dimension from not more than two tested and certified lots in the same